

PSJ15 Exh 42

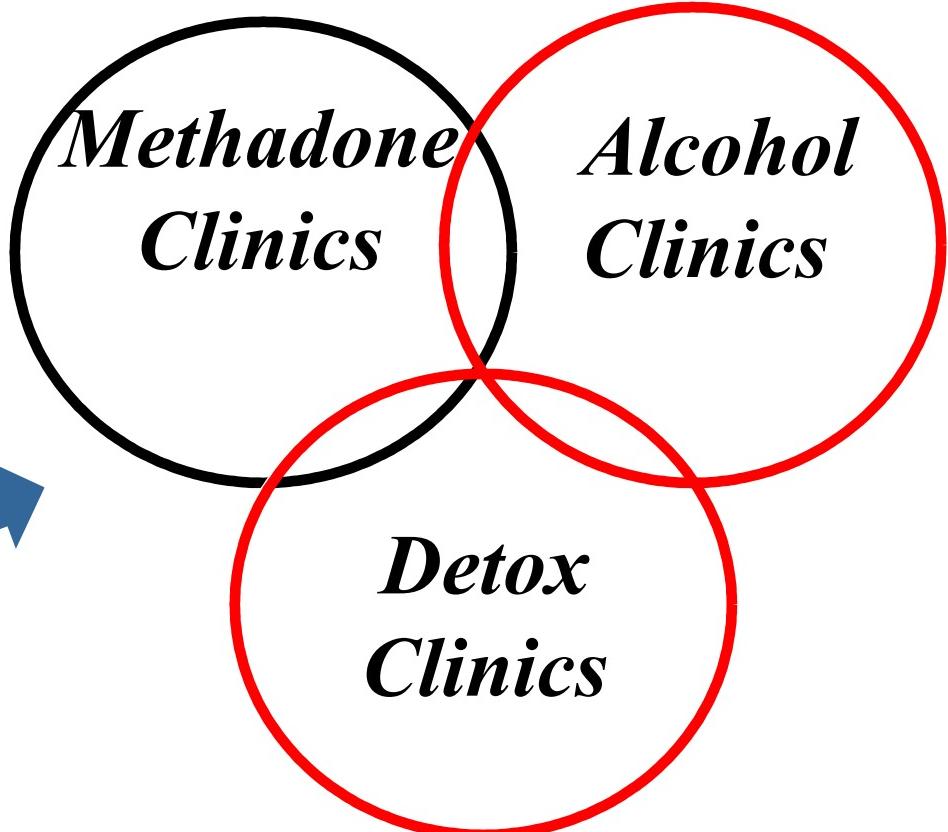
# *Agenda*

- **Addiction Treatment Business**
  - Current Status/Direction
  - Market Landscape
- **Acquisition Opportunity Overview**
  - Company Background
  - Product Information
- **Value MI Brings to the Deal**
- **Strategic Fit**
- **Financials/Assumptions**
- **Deal Structure**
- **Risk Areas**
- **Next Steps**

# AT Business

## *Current Status/Direction*

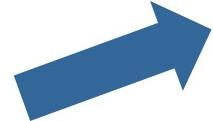
- *30 Year Old Business*
- *\$25M in Sales (+52%)*
- *MMT Market Leader (75%)*
- *Introduced Depade*
- *3 Products in the pipeline*



# AT Business

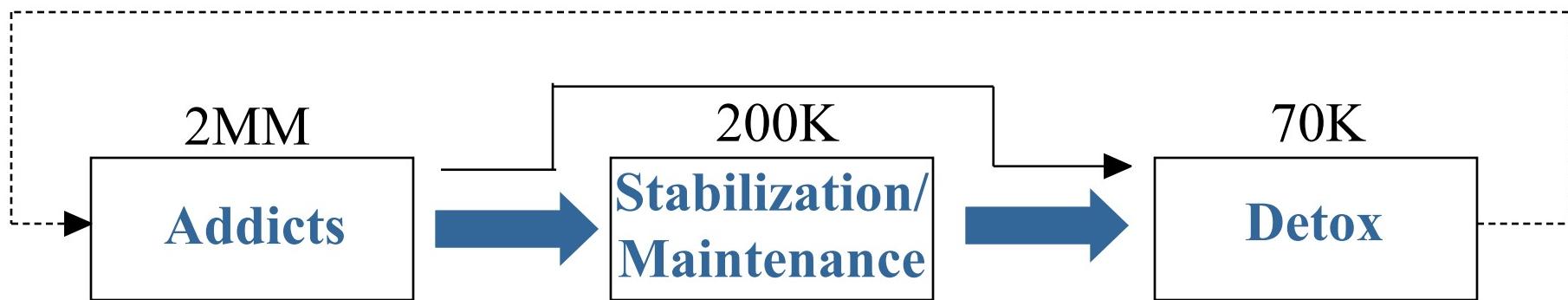
## *Current Status/Direction*

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# *AT Business*

## *Marketplace Landscape*



- Heroin
- Opiates  
(OxyContin, Vicodin)
- Synthetic Opiates  
(fentanyl, Demerol)

- Methadone
- Buprenorphine

- Cold Turkey
- Methadone 28-day
- Naltrexone (UROD)
- Clonidine (off-label)
- Lofexidine

Sites:

- MMT Clinics
- Hospital Based Detox Clinics
- In/Out Patient

# *Acquisition Opportunity*

## *Overview*

### *Britannia Pharmaceuticals*

- Based in UK
- Owned by Ajinomoto (Japan) via Forum Holdings
- Specializes in diseases for small populations
- Virtual company
- Manages business in the UK, licenses elsewhere

# *Acquisition Opportunity*

## *Overview*

### ***Lofexidine Hydrochloride***

- Indication: Alleviation of opiate withdrawal symptoms
- Form: 0.2 mg Tablet (60 Tablets/Box)  
1 Box = 1 Detox
- Duration of Treatment: 5 - 10 Days
- Approval: 1986 in UK; Marketed Since 1992
- US Approval Status: Phase III Clinicals Started; NIDA providing funding and oversight

# *MI's Value to the Deal*

- Market Leader in MMT (knowledge & experience)
  - Britannia Expects MI Will Sell More...  Royalties
- US Production Capabilities
- Regulatory Resources

# *Strategic Fit*

- **Common Call Points**
  - May Be Used In Conjunction With Other MI Products
- **Growing Market**
  - Exclusive Product
- **Improves MI's Image & Credibility**
- **MI's AT Pipeline Is Currently Light**
  - New Products Required To Maintain Market Leadership
- **Potential Use By “Pain” Physicians (Rep Detailing)**
- **Future Collaborations**

Healthcare

MALLINCKRODT

# Financials/Assumptions

	Year 0 2002-2003	Year 1 2004	Year 2 2005	Year 3 2006	Year 4 2007	Year 5 2008
<b>Volume</b>		13,200	21,000	32,500	45,000	55,000
<b>Unit Price</b>		\$140.00	\$147.00	\$154.35	\$162.07	\$170.17
<b>Net Sales</b>		\$1,783	\$2,979	\$4,841	\$7,038	\$9,032
<b>Unit Cost</b>		\$20.00	\$21.00	\$22.05	\$23.15	\$24.31
<b>Net Margin</b>		\$1,519	\$2,538	\$4,124	\$5,997	\$7,695
<b>Expenses</b>	\$800	\$1,141	\$1,739	\$2,234	\$2,819	\$3,350
- A&P	\$50	\$600	\$600	\$600	\$600	\$600
- SG&A	\$0	\$300	\$700	\$700	\$700	\$700
- Split, Misc.		\$204	\$402	\$897	\$1,482	\$2,013
- R&D, Amort.	\$750	\$37	\$37	\$37	\$37	\$37
<b>EBIT</b>	<b>(\$800)</b>	<b>\$378</b>	<b>\$799</b>	<b>\$1,890</b>	<b>\$3,178</b>	<b>\$4,345</b>

Units: Total MMT Market +4%/Yr

6% Yr. 1 Market Share (+37%/Yr.)

Price: +5%/Yr.

Expenses:

- SG&A: +2 NAMs in '04 + 2 in '05

- A&P: DTC & Thought Leader

\* Payments to BPL will be capitalized & amortized

# *Financials/Assumptions*

- 8 years for Britannia to get to 30% MMT market
- MI gets to 30% in year 8
- Britannia's progress in years 5-7
- MI ramps up faster

# *Deal Structure*

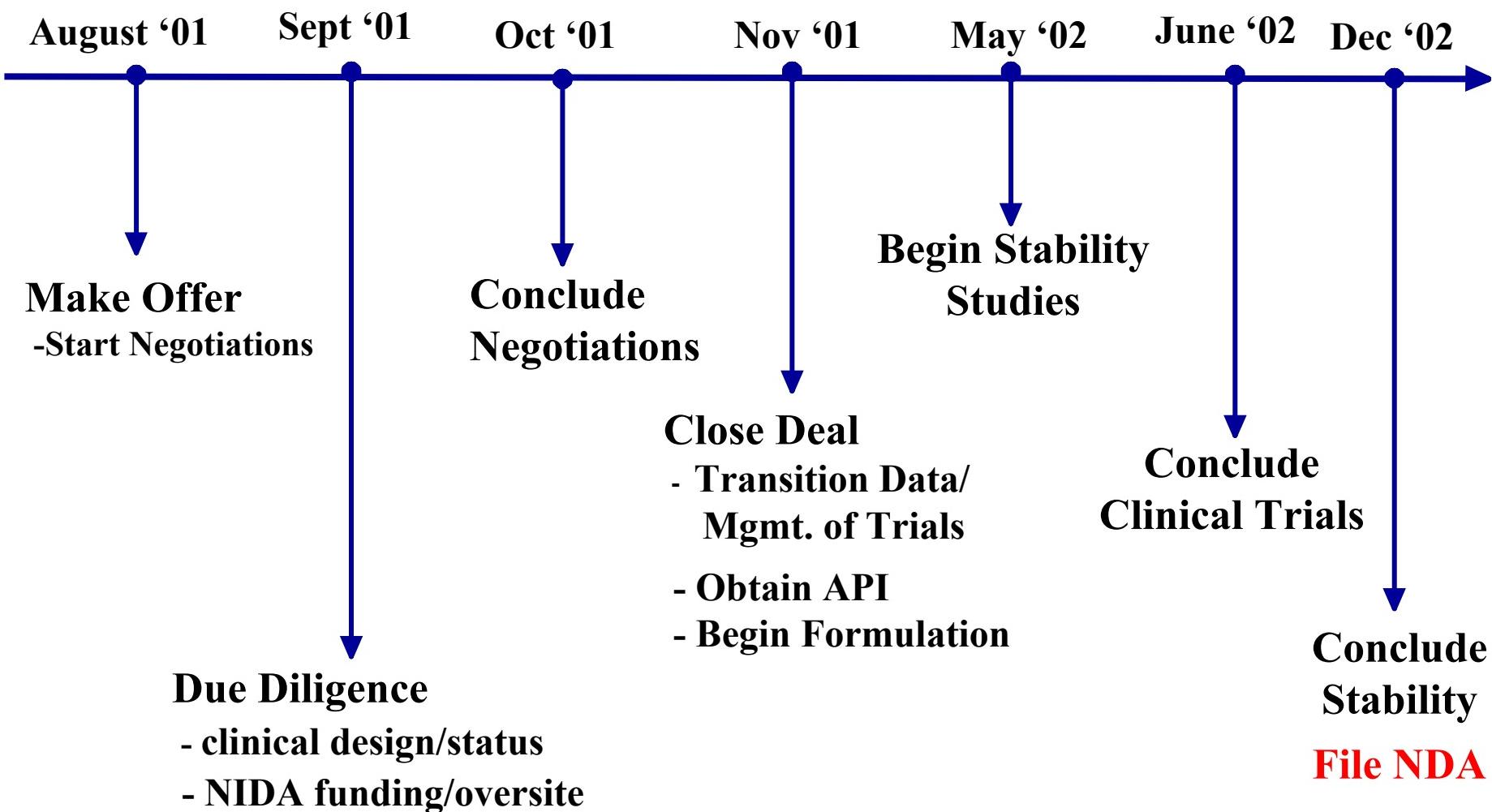
- **Milestone Payments/Timing**
  - \$350K Close FY02
  - \$250K Upon NDA filing (detox) FY03
  - \$500K Upon NDA approval (detox) FY04
  - Margin Split: MI 70%-Britannia 30%
- **MI to produce tablets, monitor Phase III trials, and file NDA**
- **Britannia (via MacFarlan Smith) to supply API to MI exclusively (in North America)**
- **Contingent on due diligence of regulatory status/progress**

# ***Risk Areas/Exposure***

- |                                       |                            |
|---------------------------------------|----------------------------|
| • <b>Design of the Trials</b>         | <b>Due Diligence</b>       |
| • <b>Adverse Events in the Trials</b> | <b>\$350K</b>              |
| • <b>Britannia Goes Under</b>         | <b>Address in Contract</b> |
| • <b>Regulatory Filing Expertise</b>  | <b>\$1.1M</b>              |
| • <b>Market Response Unknown</b>      | <b>\$1.1M</b>              |
| • <b>Raw Material Supply</b>          | <b>\$1.1M</b>              |

# *Next Steps*

## *Timeline*



- Current Product Line
  - Britaject Pen (apomorphine hydrochloride 10 mg/mL) for Parkinson's Disease
    - Recently licensed US rights to Mylan
  - Crystapen (benzylpenicillin sodium BP) for meningitis and other bacterial infections
  - OrLAAM (levacetylmethadol) for opiate addiction
    - Removed from the market earlier this year
  - BritLofex (lofexidine hydrochloride) for detoxification from opioids
- Seeking additional dosage forms and/or indications for apomorphine and lofexidine

# *Lofexidine Hydrochloride*

- Is an imidazoline derivative; an  $\alpha$  2-adrenergic agonist
- Form is a package of 60 0.2mg tablets
- MOA - when opioids are stopped abruptly, the brain produces too much noradrenaline (which is thought to cause withdrawal symptoms). Lofexidine reduces the levels of noradrenaline in thereby reducing the symptoms of withdrawal (I.e. chills, sweating, stomach cramps, diarrhea, muscle pain, runny nose and eyes).
- Length of treatment for detoxification is 5-10 days

# *Lofexidine Hydrochloride*

## *US Application*

- BPL has partnered with NIDA
  - NIDA has acted as FDA liaison since 1996
  - NIDA has provided funding
- Detoxification Indication
  - Phase III trials kicked off 1/17/01
    - Philadelphia (C. O'Brien), LA (W. Ling), and NY (H. Kleber)
  - NIDA has funded these trials
  - Potential for NDA filing in 1-2 years
  - Potential for approval in 2-3 years
  - One box=one detox

# *Lofexidine Hydrochloride*

## *US Application*

- Relapse Prevention Indication
  - Claims two brain pathways are involved
    - Drug-induced relapse - naltrexone (2 bottles of 30)
    - Stress-induced relapse - lofexidine (9 boxes of 60)
  - NIDA has funding for these trials
  - Johns Hopkins (A. Umbricht/K. Preston) and Yale (Sinha/Kosten) are the sites
  - 1-2 years behind detoxification application
- Claims of other potential indications - maintenance (methadone adjunct), alcohol, tobacco, cocaine, ADHD, etc...

# *Market Approach*

- Out-patient and in-patient programs can use (off-label use of clonidine is not good on an out-patient basis)
- MMT Clinics, Hospital Detox Programs currently using methadone (approx. 300), other addiction treatment programs
- 50% return for second detox (repeat business)
- Will be used off-label as an adjunct to methadone, buprenorphine, and naltrexone (alcohol and opiate)